UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,311	06/25/2003	Binnur Ozturk	204.001	5252

30332 7590 01/16/2007
MEREDITH & KEYHANI, PLLC
330 MADISON AVE.
6TH FLOOR
NEW YORK, NY 10017

EXAMINER	
LAMM, MARINA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,311	OZTURK ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 65-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 65-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the amendment filed 10/17/06. Claims pending are 19 and 65-83. Claims 10-64 have been cancelled. Claims 3 and 66 have been amended. Claims 68-83 have been added.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 contains the trademark/trade name "pentravan". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe some type of emollient base and, accordingly, the identification/description is indefinite. *Further, it is*

unclear what exactly is meant by "pentravan", since the specification does not describe the contents of the gel, thus, rendering the search impossible.

Claim 3 contains the trademark/trade names "pleuronic" and "lipoil". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe some type of emollient base and, accordingly, the identification/description is indefinite. *Further, it is unclear what exactly is meant by "pleuronic" since the specification does not describe the contents of the gel, thus, rendering the search impossible.*

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 4-9, 65, 67-80 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolicki (US 2004/0101582) in view of either Williams et al. (US 2003/0082214) or Murdock et al. (US 6,572,880), all of record.

Wolicki teaches transdermal compositions for the treatment of neuropathy comprising 10-50%, preferably 15-20% of ketamine, 0.001-2%, preferably 0.1-1%, of clonidine, 1-10%, preferably 2-5% of amitriptyiline, and 1-30%, preferably 3% or 6% of gabapentin. See Abstract; p. 2, [0017]-[0021]; p. 4, [0040]-[0042], [0047]; p. 8, [0089]. The carriers include cream, ointment or gel carriers. See p. 3, [0023]; p. 7, [0076]-[0078]; p. 10, [0105]. The compositions of Wolicki may additionally contain penetration enhancers. See p. 2, [0018]. The compositions are useful for relieving pain, inflammation and irritation associated with skin diseases and disorders. See p. 7, [0074]. Wolicki does not teach the claimed anti-inflammatory component. However, Williams et al. teach using non-steroidal anti-inflammatory analgesics such as acetylsalicylic acid, ketoprofen, indometacin, etc. in transdermal compositions for treating pain. See Abstract; p. 10, [0151]. Similarly, Murdock et al. teach ketoprofen in combination with gabapentin and/or amitriptyiline in transdermal compositions for pain relief. See Abstract; col. 8, lines 55-65; Examples 53-55, 63; col. 34, col. 39-40. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Wolicki such that to use an anti-inflammatory agent such as ketoprofen. One having ordinary skill in the art would have been motivated to do this to obtain an additional pain relieving effect as suggested by either Williams et al. or Murdock et al.

5. Claims 66, 81 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolicki (US 2004/0101582) in view of either Williams et al. (US 2003/0082214) or Murdock et al. (US 6,572,880) and further in view of Kobayashi et al. (EP 581 587).

Wolicki in view of either Williams et al. or Murdock et al. are applied as above. the references do not explicitly teach ibuprofen of the instant claims. However, Kobayashi et al. teach using ibuprofen in transdermal formulations for the same art-recognized purpose, i.e. as a non-steroidal anti-inflammatory drug, as ketoprofen, aspirin, indometacin and the like. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Wolicki such that to use ibuprofen instead of or in addition to ketoprofen for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain an anti-inflammatory effect as suggested by Kobayashi et al.

Response to Arguments

6. Applicant's arguments filed 4/11/06 have been fully considered but they are not persuasive.

With respect to the 112 rejection of Claims 2 and 3, the Applicant states that "claims 2-3 have been withdrawn." See p. 7/16 of the reply. In response, Claims 2 and 3 have not been cancelled by the Applicant, therefore, the rejection stands.

With respect to the 103 rejection of record, the Applicant argues that "nowhere in the Williams reference is there any suggestion or motivation to use ketoprofen." See

p. 7/16 of the reply. Further, the Applicant argues: "There is no suggestion or motivation to utilize an anti-inflammatory and in particular ketoprofen and in fact the Williams reference teaches away from their use, instead suggesting the laundry list of sodium channel blockers that does not include ketoprofen or any anti-inflammatory as in the present invention." See p. 8/16 of the reply. In response, Wolicki teaches transdermal compositions useful for relieving pain, **inflammation** and irritation associated with skin diseases and disorders as discussed above. Wolicki does not teach the claimed anti-inflammatory component. However, Williams et al. teach using non-steroidal anti-inflammatory analgesics such as acetylsalicylic acid, ketoprofen, indometacin, etc. in transdermal compositions for treating pain. Similarly, Murdock et al. teach ketoprofen in combination with gabapentin and/or amitriptyiline in transdermal compositions for pain relief. Therefore, using conventional anti-inflammatory compounds such as ketoprofen, for their art-recognized purpose, in the compositions of Wolicki would be a logical choice for one skilled in the art. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Wolicki such that to use an anti-inflammatory agent such as ketoprofen. One having ordinary skill in the art would have been motivated to do this to obtain an additional pain relieving effect as suggested by either Williams et al. or Murdock et al. It has been long held that selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results

attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

In response to the Applicant's argument that the Williams reference "teaches directly away from the present invention" (see p. 8/16 of the reply), it is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See *In re Susi*, 169 USPQ 423 (CCPA 1971). A known or obvious composition is not patentable simply because it has been described as somewhat inferior to some other product for the same use. See *In re Gurley,* 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See MPEP 2123.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
1/5/06

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER